



OW - OPP  
Harmonization and Derivation of  
Aquatic Life Screening Values:  
Growers' Perspectives

Loren J. Larson  
Managing Partner  
Caltha LLP, Minneapolis, MN

CropLife America and RISE 2011 Science and Regulatory Spring Conference | April 7, 2011



**CALTHA**



# Outline

- Background
- Why Should Growers and Applicators Be Interested?
- Areas of Concern



# Keys Differences Between OPP and OW Data Use

- Both OPP and OW use same pool of test data to evaluate risks and derive standards
- OPP and OW differ in specific testing requirements and can use/reject different data
- OPP and OW have different minimum data set requirements
  - OPP can require minimum data set from registrants
  - OW uses available data
- Method used to derive standards are different, even within programs
- Protection goals differ between OPP and OW



# OPP-OW Harmonization

- Develop a common methodology to derive “Aquatic Life Screening Values” (ALSV)
- Initial “white papers” summarizing current status, potential methodologies
  - Aquatic animal methods
  - Aquatic plant methods
  - Methods to estimate or predict toxicity
- Focus is on how to derive aquatic animal ALSV and aquatic plant ALSV with small data sets



# Why should Growers and Applicators be interested?



# Historic Regulatory Impacts

- FIFRA
  - Use registered products
  - Follow label instructions
  - Comply with State regulations
- CWA
  - Minimal direct impact
  - Voluntary stakeholders regarding impaired waters (primarily sediment and nutrient)



# Potential Regulatory Impacts

- FIFRA
  - Potential elimination of registered products based on monitoring data
  - Additional label requirements or use restrictions
  - State restrictions, required or voluntary BMPs
- CWA
  - More surface waters listed as impaired due to herbicides, insecticides, etc.
  - Restricted uses under State or EPA Pesticide Application NPDES general permits
  - Prohibited use and discharge to listed impaired waters



# Use of WQ Benchmarks

## Minnesota Example

- Minnesota Pesticide Management Plan
- Selecting reference values to interpret surface water monitoring data
  - Preference is to compare pesticide monitoring data to promulgated State Water Quality Standard
  - In the absence of State Water Quality Standard, “reference values” from the EPA or other states will be considered





# Use of WQ Benchmarks

## Minnesota Example

- If monitoring data exceed 10%-50% of reference value, “preventive measures” are considered
  - Development of voluntary pesticide-specific BMPs to protect surface waters from further contamination,
- MDA has authority to take additional action to prevent any unreasonable adverse effects on the environment including impacts to surface waters,
- MDA can approve, deny or cancel the registration of any pesticide and can impose state use and distribution restrictions to prevent unreasonable adverse effects on the environment.



# Areas of Concern



# 1. Using Screening Methods To Set Legally Enforceable Water Quality Standards

- Intended use of ALSV to set water quality standards under CWA

*“ALSVs ...may be used by States and Tribes in the development of water quality standards.”, Animal paper, page 5, 24.*

*“ALSV may be considered by USEPA, States and Tribes to derive scientifically defensible water quality standards...”, Animal paper, page 7, 28, 29*

*“This paper also provides a conceptual approach that may be used to integrate chemical-specific data, tools and methods for deriving community level benchmarks (i.e., ALSVs) that may be used by USEPA, States and Tribes to derive scientifically defensible water quality criteria ”, Animal paper, page 32.*

- *Additional intended use of ALSV as screening tool and in risk assessment*

*“ALSVs may be used to screen concentrations of pesticides and effluents in ambient waters.”, Animal paper, page 5, 24;*

*“These additional methods may be used to augment the ability of the USEPA, as well as states, local and tribal water management agencies to derive taxa-based and cross-taxa (community-based) toxicity benchmark values for chemicals, such as pesticides, for risk assessment, monitoring and diagnostic purposes. ”, Animal paper, page 6;*

*“...additional tools and approaches that may be used to augment the ability of the EPA, and states, local and tribal water management agencies to derive taxa specific and cross-taxa (community) benchmark values for chemicals such as pesticides.”, Plant paper, page 5..*



# 1. Using Screening Methods To Set Legally Enforceable Water Quality Standards

- A method used to develop legally enforceable water quality standards needs to be more rigorous compared to a method used to develop screening values.
- Therefore, if the intent is to develop a method to derive ALSV to be used as both standards and screening values, a more rigorous analysis will be required to assure ALSV do not over or under estimate effects



## 2. Data Acceptability Requirements Between OPP and OW Are Not Adequately Addressed

- Assumption that data sets used by OPP and OW are the same

*“Currently, both OPP and OW rely on the same aquatic toxicity test results (e.g., scientific literature, registrant-submitted studies)”, Animal paper, page 5.*

*“Although the assessment endpoints of OPP and OW differ ... they both rely upon similar aquatic toxicity test results. ”, Animal paper, page 6.*

- Current OW data acceptance criteria exclude some data accepted by OPP
- Use of “greater than” values, used in OPP screening assessments



### 3. Key Issues Regarding Use of Plant Data Are Not Adequately Addressed

- Recovery and reversal of impacts unique to plants
- Inconsistent use of plant test end-points
  - $EC_{50}$ ,  $EC_{20}$ , NOAEC
- Are community protection goals and return frequencies comparable for aquatic animals and aquatic plants?
  - Under CWA, protection goal for aquatic animals is to protect down to 5<sup>th</sup> percentile, with three year return frequency



## 4. Stated Criteria For Evaluation of Methodologies Are Inconsistent

- Protection goals should be consistent with CWA
  - 5<sup>th</sup> percentile, 3 year recovery
- EPA describes its intent to develop a methodology that would result in a more conservative (i.e. lower) ASLV compared to a methodology that would approximate the 5<sup>th</sup> percentile (HC<sub>5</sub>).
- Current OW methods estimate most likely value for HC<sub>5</sub>; methods are discussed to estimate lower 95<sup>th</sup> percentile confidence limit of HC<sub>5</sub>



## 5. Implementation and Uses of Methodologies Under FIFRA - CWA Inadequately Addressed

- Alternative methodologies to derive ALSV need to address intended implementation and uses of the ALSV by EPA, States and Tribes.
  - Should aquatic animal and aquatic plant ALSV be used interchangeably?
  - Are averaging periods equivalent?





## 6. Use of Predicted or Estimated Values

- In the absence of actual test data, EPA is exploring the use of predicted or calculated toxicity data, to fill some or all minimum data needs
- Concern is that, based on EPA's assessment of the accuracy of these predictive methods, use of predicted or calculated data adds significant uncertainty to calculation of ALSVs, as well as a bias to over estimating the toxicity of chemicals.



## 6. Use of Predicted or Estimated Values

- EPA's preliminary evaluation of the accuracy of the predictive methodologies
  - Predicted LC50s between various fish species used regressions with fairly low  $r^2$  values, ranging from 0.311 to 0.825, with an average of 0.56.
  - ALSV calculations resulted in ALSVs ranging from about 1.4- to 9.2-fold lower than those calculated using experimentally determined toxicity data. On average, using predicted values resulted in approximately a 5-fold lower ALSV.



## 7. Use of Unqualified Data and Requirement For Minimum Data Set

- Not clear that minimum data set and data quality requirements will be established

*“regulatory agencies must have the flexibility to characterize the potential ... effects of chemicals using the available data even if those data are limited in quantity.” Animal paper, page 6*

*“In practice, however, data from any “reasonable” test procedure are often included in aquatic plant sensitivity distributions... The need to characterize the range of sensitivities in the aquatic plant community may outweigh the desire for comparable test conditions.” Plant paper, page 27*



# Why should growers be concerned?

Minnesota example – Acetochlor

State Water Quality Standard 3.6  $\mu\text{g/L}$



# Why should growers be concerned?

Minnesota example – Acetochlor  
State Water Quality Standard 3.6 µg/L

Mean concentration (2004-2009)	<0.17 µg/L	<ul style="list-style-type: none"><li>• Median &lt;0.050 µg/L</li><li>• ND for 71% of samples</li><li>• 2,030 samples collected 2004- 2009</li></ul>
% of samples exceeding WQ standard	0.4%	<ul style="list-style-type: none"><li>• 9 samples collected on 4 rivers</li></ul>
% of samples above <b>high range</b> of action under MDA Pesticide Mgmt. Plan	1%	<ul style="list-style-type: none"><li>• 24 samples collected on 12 rivers</li></ul>
% of samples above <b>low range</b> of action under MDA Pesticide Mgmt. Plan	9%	<ul style="list-style-type: none"><li>• 187 samples collected on 34 rivers</li></ul>



# Why should growers be concerned?

Minnesota example – Acetochlor

Hypothetical ALSV = 0.72  $\mu\text{g}/\text{L}$  (assumes 5x overestimate of effects)



# Why should growers be concerned?

Minnesota example – Acetochlor

Hypothetical ALSV = 0.72  $\mu\text{g/L}$  (assumes 5x overestimate of effects)

	Current WQ Standard	Hypothetical WQ Standard
% of samples exceeding WQ standard	0.4%	5 %
% of samples above <b>high range</b> of action under MDA Pesticide Mgmt. Plan	1 %	9 %
% of samples above <b>low range</b> of action under MDA Pesticide Mgmt. Plan	9 %	23 %



# Questions

**Contact:**

**Loren Larson**

**Caltha LLP**

**Minneapolis, Minnesota**

**(763) 208-6430**

**[llarson@calthacompany.com](mailto:llarson@calthacompany.com)**

